REMARKS

Upon entry of the above amendment, claims 1, 4, 5, 6, 7, 13, 19, 20, 80, 84, 85, 91 and 95 will be pending in this application.

Claims 1, 91 and 95 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by New *et al.*, WO 98/001169 A1 (hereinafter, the "New reference").[1] The Office Action alleges that the New reference anticipates the claims because it discloses a formulation comprising an emulsion that comprises a bile salt. Office Action at page 3.

The standard for anticipation under §102 is one of strict identity. An anticipation rejection requires a showing that each element of a claim be found in a single reference. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). Further, it has been well established that in order for a genus to anticipate a species under 35 U.S.C. 102, one of ordinary skill in the art must be able to "at once envisage" the species within the generic disclosure. See, for example, *Ex parte A*, 17 U.S.P.Q.2d 1716 (Bd. Pat. App. & Inter. 1990). One of ordinary skill in the art must be able to, for example, write the name of each of the species included in the genus before any of the species can be "at once envisaged." See also *In re Meyer*, 599 F.2d 1026, 1031, 202 U.S.P.Q. 175, 179 (C.C.P.A.1979) which finds that a prior art genus does not "identically disclose or describe, within the meaning of 102" the claimed species "since the genus would include an untold number of species." While these cases refer to chemical species and genera, the concepts therein are applicable to the presently claimed formulations and compositions. For example, in order to anticipate a claimed formulation, that formulation must be capable of being "at once envisaged" by one skilled in the art from a broad genus of formulations.

The formulations of the present invention are not anticipated by the New reference because one skilled in the art could not "at once envisage" a formulation

[1] Applicants respectfully assert that the rejection over the New reference should have been made under 35 U.S.C. §102(a), not (e), because the New reference (which is a publication, not a patent) was filed prior to November 29, 2000.

corresponding to the claimed invention from among the myriad formulations reported in the New reference.

The formulations of the New reference are numerous and diverse. Generally, the New reference discloses a hydrophobic formulation. The hydrophobic formulation comprises medium chain monoglycerides, amphiphiles and hydrophilic species. The specification identifies a number of possible medium chain monoglycerides, amphiphiles, and hydrophilic species. For example, an amphiphile may be a phosphatidyl choline, phosphatidic acid, phosphatidyl glycerol, etc. Also among the possible amphiphiles listed is bile salt. The New reference at page 4.

The New reference also discloses that the hydrophobic formulation may be combined with an aqueous phase to form an emulsion. The New reference at page 9. Further, the New reference lists a number of macromolecules that may be included in the formulation. Among the possible macromolecules listed is an oligonucleotide. The New reference at page 9.

Within this broad disclosure, one can hardly count the number of possible formulations proposed, much less "at once envisage" the formulations of the claimed invention. Indeed, when one considers only the emulsion formulations of the New reference, the combination of medium chain monoglycerides, amphiphiles, hydrophilic species and aqueous phase can make hundreds of different emulsion formulations.

Thus, it appears that in making the present rejection, the Office Action has improperly picked a specific formulation combination in relation to the emulsion/bile/oligonucleotide components of the present formulations from among innumerable combinations in the New reference. Accordingly, the New reference does not anticipate the present invention, and Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 102(e).

Claims 1, 4-7, 13, 19-20, 84-85, 91 and 95 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kawai et al., Japanese Patent Application No. 7-330614 (hereinafter "the Kawai reference") in view of the New reference and Nielsen et al., WO 97/13528 (hereinafter "Nielson reference").

Applicants respectfully assert that the Office Action has not established a prima facie case of obviousness because the Kawai reference alone, or in combination with the New reference and/or the Nielson reference, does not teach or suggest the claimed formulations. As the Office Action admits, the Kawai reference does not disclose a formulation comprising a bile (Office Action at page 6). The New reference does not cure this deficiency, because as discussed above, one cannot "at once envisage" a formulation comprising an emulsion and a bile salt from the disclosure of the New reference. The Nielson reference also does not cure the deficiencies of the Kawai reference because Office Action has not identified a formulation comprising a bile salt in the Nielson reference. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

Claim 80 is rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking support in the specification. Specifically, the Office Action is alleging that the recitation "oligonucleotide comprises SEQ ID NO: 1" as it relates to the claimed composition is not supported by the specification. To the contrary, the recitation at issue is fully supported by the specification. For example, the specification at page 3, paragraph 5, discloses that:

> the present invention provides pharmaceutical compositions comprising at least one ... nucleic acid. The nucleic acid can be ... an oligonucleotide.

The specification at page 16, paragraph 46, further discloses that:

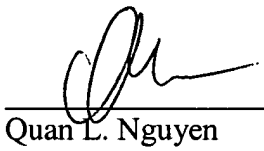
> Oligonucleotides may comprise nucleotide sequences sufficient in identity and number to effect specific hybridization with a particular nucleic acid. Such oligonucleotides which specifically hybridize to a portion of the sense strand of a gene are commonly described as "antisense."

Page 18 and 19, paragraphs 49-51, discloses that SEQ ID NO: 1 is an "antisense." Thus, the recitation "oligonucleotide comprises SEQ ID NO: 1" as it relates to the claimed

composition in claim 80 is fully supported by the specification. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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